



HYPHEN BioMed
155 rue d'Eragny
95000 Neuville-sur-Oise
France

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002K

Lot No. : FD1993MX

Expiration date : 2027-03-27

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FD1993APMX	2027-03-27
R2 : Human Calcium Thrombin	3 vials	FD1993AQMXX	2027-04-04

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 50 ± 10 sec	50.9 sec
	$R^2 \geq 0.98$	PASS
	Controls measured in acceptance ranges	PASS
Normal Plasma	Dabigatran conc. < 10 ng / mL	PASS

Calibration Curve for information

Standard Range

Dabigatran Conc.-ng/mL	0	270	544
CT (Sec.) STAR	27.3	56.2	88.8
CT (Sec.) CS	39.3	73.4	115.3

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[82-122]	95
C2	[213-289]	231

Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.) STAR	25.7	45.5	76.5
CT (Sec.) CS	38.2	56.2	84.6

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[16-36]	25
C2	[54-82]	64

* TV= Target Value - MV= Measured Value

This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Quality Control Approval

Date of Approval :

29 OCT. 2024

S. LECOURT

Quality Control Manager :